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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,693	07/03/2000	HANS PETER ZENNER	24218	3546
20529	7590	09/15/2006		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,693

Applicant(s)

ZENNER ET AL.

Examiner

Andrew D. Kosar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-16,21 and 22 is/are pending in the application.
4a) Of the above claim(s) 7,8,10 and 11 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4,6,9,12-16,21 and 22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed June 29, 2006 are acknowledged and have been fully considered.

Claims 1, 4, 6-16, 21 and 22 are pending.

Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 7, 8, 10 and 11 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 28, 2005.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6, 9, 12-16, 21 and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over FOULON in view of SERRADEIL-LE GAL, for the reasons of record and those set forth below.

Applicant's amendments to the claims incorporate rejected limitations into the independent claim, and thus do not alter the rejection set forth in the previous Office Action.

Applicant argues that no *prima facie* case of obviousness has been set forth because the presence of vasopressin receptors in the inner ear were not known at the time of the invention and that, "Only these results of the inventors of the instant application obtained directly at the inner ear could show a person skilled in the art that vasopressin-V₂-receptor antagonists are

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useful for the treatment of disturbances or illnesses of the inner ear.” Further alleging that, “It is under these preconditions that the art cited by the examiner has to be evaluated.” (page 11, *Remarks*).

Additionally, Applicant argues that Foulon does not teach any examples of using the compounds to treat anything, but rather provides, “a very general listing of a huge amount of totally different conditions for which these compounds are allegedly effective. However, there is no proof of the efficacy of the disclosed compound in the treatment of these conditions. As a consequence, the corresponding disclosure of Foulon is merely theoretical.” (page 12, *Remarks*).

Applicant further argues that Serradeail-Le Gal does not remedy the deficiencies of Foulon.

Applicant’s arguments have been fully considered, but are not found persuasive.

With respect to Serradeail-Le Gal, the examiner has provided this reference to show that the compound was known to be a vasopressin-V₂-receptor antagonist at the time of the invention, and it is not relied upon to rectify any deficiencies in Foulon *per se*, as the teaching of Foulon set forth the *prima facie* case of obviousness.

With respect to Foulon, it appears as if Applicant is arguing that Foulon is not enabled for the treating Menière’s syndrome, however patents and their claims are presumed to be valid, i.e.- enabled. The specification teaches the diseases/conditions embraced by the claimed method (column 24, lines 28-67), one specifically enumerated is Menière’s syndrome, which as stated in the previous Office Action, is a disease/condition associated with vertigo, low frequency hearing impairment, tinnitus and hydrops (*see page 8, Office Action; mailed 12/30/05*). Additionally, contrary to Applicant’s assertion, the list of diseases in Foulon is not a

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'huge amount of totally different conditions', but rather a list of diseases within the scope of the claimed invention.

Thus, because the patent is presumed valid, one of skill in the art would have immediately recognized that one could treat any disease listed, including Menière's syndrome, with the claimed compounds. Additionally, one would have been motivated to treat any disease listed, including Menière's syndrome, with the claimed compounds, and had a reasonable had a reasonable expectation for success in doing so, because Foulon claims the method and specifically teaches that the compounds of the invention can be used to treat any of the listed diseases, including Menière's syndrome.

Claims 13 remains objected to for reciting a chemical formula without matching braces. The leading square bracket '1-[4-(N-...' does not have a corresponding right square bracket ']', nor does the square bracket at 'spiro-[4-(s-...' have a corresponding right square bracket.

Appropriate correction is required.

Conclusion

NO CLAIMS ARE ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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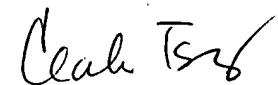
This application contains claims 7, 8, 10 and 11 drawn to an invention nonelected with traverse on September 28, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Andrew D. Kosar, Ph.D.
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